

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

AMY W. SCHULMAN  
DLA PIPER LLP  
1251 Avenue of the Americas  
New York, NY 10020  
Telephone: (212) 335-4500  
Facsimile: (212) 335-4501  
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)  
GORDON & REES LLP  
Embarcadero Center West  
275 Battery Street, Suite 2000  
San Francisco, CA 94111  
Telephone: (415) 986-5900  
Facsimile: (415) 986-8054  
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)  
TUCKER ELLIS & WEST LLP  
515 South Flower Street, Suite 4200  
Los Angeles, CA 90071-2223  
Telephone: (213) 430-3400  
Facsimile: (213) 430-3409  
michael.zellers@tuckerellis.com

Attorneys for Defendants  
PFIZER INC., PHARMACIA CORPORATION,  
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

*This document relates to*

ARMAN ALPIAN, et al.,

Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,  
and G.D. SEARLE, LLC, (FKA G.D. SEARLE &  
CO.),

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-1703-CRB

) **PFIZER INC., PHARMACIA**  
) **CORPORATION, AND G.D.**  
) **SEARLE LLC'S ANSWER TO**  
) **COMPLAINT**

) **JURY DEMAND ENDORSED**  
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as  
 2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC  
 3 (improperly captioned in Plaintiffs' Complaint as "G.D. Searle, LLC") ("Searle"), (collectively  
 4 "Defendants") and file this Answer to Plaintiffs' Complaint ("Complaint"), and would  
 5 respectfully show the Court as follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs and Decedent were  
 9 prescribed or used Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only  
 10 be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals  
 11 the specific time periods in which Plaintiffs and Decedent were prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,  
 15 Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny  
 16 that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain  
 17 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United  
 18 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
 19 accordance with their approval by the FDA. Defendants admit that, during certain periods of  
 20 time, Celebrex® was manufactured and packaged for Searle, which developed, tested,  
 21 marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by  
 22 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
 23 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used  
 24 in accordance with its FDA-approved prescribing information. Defendants state that the  
 25 potential effects of Celebrex® were and are adequately described in its FDA-approved  
 26 prescribing information, which was at all times adequate and comported with applicable  
 27 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
 28 Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of

1 the Complaint.

2 **Response to Allegations Regarding Parties**

3 1. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' age, and  
5 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this  
6 paragraph of the Complaint.

7 2. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
8 business in New York. Defendants admit that, as the result of a merger in April 2003,  
9 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph  
10 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants  
11 are without knowledge or information sufficient to form a belief as to the truth of such  
12 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of  
13 time, Pfizer marketed and co-promoted Celebrex® in the United States, including New York,  
14 Florida, Alabama, Arizona, and California, to be prescribed by healthcare providers who are by  
15 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
16 deny the remaining allegations in this paragraph of the Complaint.

17 3. Defendants admit that Searle is a Delaware limited liability company with its principal  
18 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,  
19 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
20 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
21 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
22 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
23 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
24 the remaining allegations in this paragraph of the Complaint.

25 4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
26 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as  
27 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
28 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted

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San Francisco, CA 94111

1 Celebrex® in the United States, including New York, Florida, Alabama, Arizona, and  
2 California, to be prescribed by healthcare providers who are by law authorized to prescribe  
3 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
4 allegations in this paragraph of the Complaint.

5 5. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
6 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
7 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
8 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
9 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
10 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
11 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
12 that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle  
13 and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this  
14 paragraph of the Complaint.

15 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
16 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
17 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
18 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
19 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
20 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state  
22 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved  
23 prescribing information. Defendants state that the potential effects of Celebrex® were and are  
24 adequately described in its FDA-approved prescribing information, which was at all times  
25 adequate and comported with applicable standards of care and law. Defendants deny any  
26 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27 7. Defendants state that the allegations in this paragraph of the Complaint regarding  
28 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or

1 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
2 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Allegations Regarding Jurisdiction and Venue**

4 8. Defendants are without knowledge or information to form a belief as to the truth of the  
5 allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount  
6 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim  
7 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of  
8 interests and costs.

9 9. Defendants are without knowledge or information to form a belief as to the truth of the  
10 allegations in this paragraph of the Complaint regarding the judicial district in which the  
11 asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex®  
12 was and is safe and effective when used in accordance with its FDA-approved prescribing  
13 information. Defendants deny committing a tort in the States of New York, Florida, Alabama,  
14 Arizona, and California, and deny the remaining allegations in this paragraph of the Complaint.

15 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
16 and co-promoted Celebrex® in the United States, including New York, Florida, Alabama,  
17 Arizona, and California, to be prescribed by healthcare providers who are by law authorized to  
18 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during  
19 certain periods of time, Celebrex® was manufactured and packaged for Searle, which  
20 developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be  
21 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
22 with their approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle are  
23 registered to and do business in the States of New York, Florida, Alabama, Arizona, and  
24 California. Defendants state that the allegations in this paragraph of the Complaint regarding  
25 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
26 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
27 the same. Defendants deny committing a tort in the States of New York, Florida, Alabama,  
28 Arizona, and California, and deny the remaining allegations in this paragraph of the Complaint.

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**Response to Allegations Regarding Interdistrict Assignment**

11. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

**Response to Factual Allegations**

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship, medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.

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1 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
2 FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
6 and deny the remaining allegations in this paragraph of the Complaint.

7 15. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
9 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
10 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
11 FDA-approved prescribing information. Defendants state that the potential effects of  
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
15 and deny the remaining allegations in this paragraph of the Complaint.

16 16. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's  
18 age and citizenship, and, therefore, deny the same. Defendants are without knowledge or  
19 information sufficient to form a belief as to the truth of the allegations in this paragraph of the  
20 Complaint regarding whether Plaintiff is the surviving heir of Decedent, whether Plaintiff the  
21 Representative of Decedent's Estate, and whether Plaintiff has standing to bring this suit, and,  
22 therefore, deny the same. Defendants are without knowledge or information sufficient to form  
23 a belief as to the truth of the allegations in this paragraph of the Complaint regarding  
24 Decedent's medical condition and whether Decedent used Celebrex®, and, therefore, deny the  
25 same. Defendants state that Celebrex® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent  
2 injury or damage, and deny the remaining allegations in this paragraph of the Complaint,  
3 including all subparts.

4 17. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
6 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
7 and is safe and effective when used in accordance with its FDA-approved prescribing  
8 information. Defendants state that the potential effects of Celebrex® were and are adequately  
9 described in its FDA-approved prescribing information, which was at all times adequate and  
10 comported with applicable standards of care and law. Defendants deny that Celebrex® caused  
11 Plaintiffs or Decedent injury or damage and deny the remaining allegations in this paragraph of  
12 the Complaint.

13 18. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
15 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
16 and is safe and effective when used in accordance with its FDA-approved prescribing  
17 information. Defendants state that the potential effects of Celebrex® were and are adequately  
18 described in its FDA-approved prescribing information, which was at all times adequate and  
19 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
20 deny that Celebrex® caused Plaintiffs or Decedent injury or damage and deny the remaining  
21 allegations in this paragraph of the Complaint.

22 19. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
24 Decedent used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary  
25 case, Celebrex® was expected to reach users and consumers without substantial change from  
26 the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 20. Defendants are without knowledge or information sufficient to form a belief as to the  
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and

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1 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
2 and is safe and effective when used in accordance with its FDA-approved prescribing  
3 information. Defendants state that the potential effects of Celebrex® were and are adequately  
4 described in its FDA-approved prescribing information, which was at all times adequate and  
5 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
6 and deny the remaining allegations in this paragraph of the Complaint.

7 21. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Decedent left  
9 survivors as defined by law and whether Plaintiffs and Decedent used Celebrex® and,  
10 therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when  
11 used in accordance with its FDA-approved prescribing information. Defendants state that the  
12 potential effects of Celebrex® were and are adequately described in its FDA-approved  
13 prescribing information, which was at all times adequate and comported with applicable  
14 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
15 Plaintiffs, Decedent, Decedent's Estates, Decedent's surviving spouses, and Decedent's  
16 surviving children injury or damage, and deny the remaining allegations in this paragraph of the  
17 Complaint, including all subparts.

18 22. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
19 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
20 Complaint.

21 23. Defendants state that the allegations in this paragraph of the Complaint regarding  
22 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no  
23 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,  
24 referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants deny the  
25 remaining allegations in this paragraph of the Complaint.

26 24. Defendants state that the allegations in this paragraph of the Complaint are not directed  
27 towards Defendants and, therefore, no response is required. To the extent that a response is  
28 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the

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1 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
2 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

3 25. Defendants state that the allegations in this paragraph of the Complaint are not directed  
4 towards Defendants and, therefore, no response is required. To the extent that a response is  
5 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
6 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
7 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

8 26. Defendants state that the allegations in this paragraph of the Complaint are not directed  
9 towards Defendants and, therefore, no response is required. To the extent that a response is  
10 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
11 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
12 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

13 27. Defendants state that the allegations in this paragraph of the Complaint regarding “other  
14 pharmaceutical companies” are not directed towards Defendants and, therefore, no response is  
15 required. To the extent a response is deemed required, Defendants state that, as stated in the  
16 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to  
17 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2  
18 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the  
19 cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiffs fail to provide the proper context for the  
20 remaining allegations in this paragraph and Defendants therefore lack sufficient information or  
21 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining  
22 allegations in this paragraph of the Complaint.

23 28. Defendants state that the allegations in this paragraph of the Complaint regarding  
24 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or  
25 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
26 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he  
27 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,  
28 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in

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1 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants  
2 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
3 approved prescribing information. Defendants state that the potential effects of Celebrex®  
4 were and are adequately described in its FDA-approved prescribing information, which was at  
5 all times adequate and comported with applicable standards of care and law. Defendants deny  
6 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

7 29. Defendants admit that Searle submitted a New Drug Application (“NDA”) for  
8 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted  
9 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of  
10 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.  
11 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to  
12 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis  
13 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny  
14 the remaining allegations in this paragraph of the Complaint.

15 30. Defendants admit that Celebrex® was launched in February 1999. Defendants admit  
16 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted  
17 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
18 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
19 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,  
20 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States  
21 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
22 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe  
23 and effective when used in accordance with its FDA-approved prescribing information.  
24 Defendants state that the potential effects of Celebrex® were and are adequately described in its  
25 FDA-approved prescribing information, which was at all times adequate and comported with  
26 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
27 remaining allegations in this paragraph of the Complaint.

28 31. Defendants state that the referenced article speaks for itself and respectfully refer the

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1 Court to the article for its actual language and text. Any attempt to characterize the article is  
2 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
4 this paragraph of the Complaint.

5 32. Defendants state that the referenced article speaks for itself and respectfully refer the  
6 Court to the article for its actual language and text. Any attempt to characterize the article is  
7 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
9 this paragraph of the Complaint.

10 33. Defendants state that the referenced FDA Update speaks for itself and respectfully refer  
11 the Court to the FDA Update for its actual language and text. Any attempt to characterize the  
12 FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when  
13 used in accordance with its FDA-approved prescribing information. Defendants state that the  
14 potential effects of Celebrex® were and are adequately described in its FDA-approved  
15 prescribing information, which was at all times adequate and comported with applicable  
16 standards of care and law. Defendants deny the remaining allegations in this paragraph of the  
17 Complaint.

18 34. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants deny the remaining allegations in this paragraph of the Complaint.

23 35. Defendants state that Celebrex® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendants state that the potential effects of  
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
28 the Complaint.

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36. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. Defendants admit that a Medical Officer Review dated September 20, 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

41. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that the referenced article speaks for itself and respectfully refer the

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1 Court to the article for its actual language and text. Any attempt to characterize the article is  
2 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
3 paragraph of the Complaint.

4 43. Defendants state that the referenced articles speak for themselves and respectfully refer  
5 the Court to the articles for their actual language and text. Any attempt to characterize the  
6 articles is denied. Defendants deny the remaining allegations in this paragraph of the  
7 Complaint.

8 44. Defendants state that the referenced article speaks for itself and respectfully refer the  
9 Court to the article for its actual language and text. Any attempt to characterize the article is  
10 denied. Defendants state that the referenced study speaks for itself and respectfully refer the  
11 Court to the study for its actual language and text. Any attempt to characterize the study is  
12 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 45. Defendants state that the referenced Medical Officer Review speaks for itself and  
14 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
15 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
16 allegations in this paragraph of the Complaint.

17 46. Plaintiffs fail to provide the proper context for the allegations concerning “Public  
18 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
19 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
20 Defendants deny the remaining allegations in this paragraph of the Complaint.

21 47. Defendants state that the referenced article speaks for itself and respectfully refer the  
22 Court to the article for its actual language and text. Any attempt to characterize the article is  
23 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
24 paragraph of the Complaint.

25 48. Defendants state that the referenced study speaks for itself and respectfully refer the  
26 Court to the study for its actual language and text. Any attempt to characterize the study is  
27 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public  
28 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or

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1 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 49. Defendants admit that there was a clinical trial called APC. Defendants state that the  
4 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
5 language and text. Any attempt to characterize the article is denied. Defendants deny the  
6 remaining allegations in this paragraph of the Complaint.

7 50. Defendants state that the referenced article speaks for itself and respectfully refer the  
8 Court to the article for its actual language and text. Any attempt to characterize the article is  
9 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Data Safety  
10 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient  
11 information or knowledge to form a belief as to the truth of such allegations and, therefore,  
12 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 51. Defendants state that the referenced article speaks for itself and respectfully refer the  
14 Court to the article for its actual language and text. Any attempt to characterize the article is  
15 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 52. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
17 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
18 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 53. Defendants state that the referenced Medical Officer Review speaks for itself and  
21 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
22 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
23 allegations in this paragraph of the Complaint.

24 54. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide  
25 the proper context for the allegations concerning “other Celebrex trials” contained in this  
26 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
27 form a belief as to the truth of such allegations and, therefore, deny the same. As for the  
28 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state

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1 that the referenced study speaks for itself and respectfully refer the Court to the study for its  
2 actual language and text. Any attempt to characterize the study is denied. Defendants deny the  
3 remaining allegations in this paragraph of the Complaint.

4 55. Defendants state that the referenced article speaks for itself and respectfully refer the  
5 Court to the article for its actual language and text. Any attempt to characterize the article is  
6 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 56. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the  
8 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants  
9 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
10 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for  
11 themselves and respectfully refer the Court to the studies for their actual language and text.  
12 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in  
13 this paragraph of the Complaint.

14 57. Defendants state that the referenced Medical Officer Review speaks for itself and  
15 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
16 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
17 allegations in this paragraph of the Complaint.

18 58. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint  
19 are not directed toward Defendants, and therefore no response is required. To the extent that a  
20 response is deemed required, Plaintiffs fail to provide the proper context for the allegations in  
21 this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.  
22 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of  
23 such allegations and, therefore, deny the same. Defendants state that the referenced study  
24 speaks for itself and respectfully refer the Court to the study for its actual language and text.  
25 Any attempt to characterize the study is denied. Defendants deny the remaining allegations in  
26 this paragraph of the Complaint.

27 59. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the  
28 Complaint are not directed toward Defendants, and therefore no response is required. To the

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1 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the  
2 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph  
3 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a  
4 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the  
5 referenced study speaks for itself and respectfully refer the Court to the study for its actual  
6 language and text. Any attempt to characterize the study is denied. Defendants deny the  
7 remaining allegations in this paragraph of the Complaint.

8 60. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the  
9 Complaint are not directed toward Defendants, and therefore no response is required. To the  
10 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the  
11 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph  
12 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a  
13 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the  
14 referenced study speaks for itself and respectfully refer the Court to the study for its actual  
15 language and text. Any attempt to characterize the study is denied. Defendants state that the  
16 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
17 language and text. Any attempt to characterize the article is denied. Defendants deny the  
18 remaining allegations in this paragraph of the Complaint.

19 61. Defendants state that Celebrex® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendants deny the allegations in this  
21 paragraph of the Complaint.

22 62. Defendants state that the referenced article speaks for itself and respectfully refer the  
23 Court to the article for its actual language and text. Any attempt to characterize the article is  
24 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 63. Defendants state that allegations in this paragraph of the Complaint are not directed  
26 toward Defendants, and therefore no response is required. To the extent that a response is  
27 deemed required, Defendants state that the referenced article speaks for itself and respectfully  
28 refer the Court to the article for its actual language and text. Any attempt to characterize the

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1 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 64. Defendants deny the allegations in this paragraph of the Complaint.

3 65. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
8 remaining allegations contained in this paragraph of the Complaint.

9 66. Defendants deny any wrongful conduct and deny the allegations contained in this  
10 paragraph of the Complaint.

11 67. Defendants deny any wrongful conduct and deny the allegations contained in this  
12 paragraph of the Complaint.

13 68. Defendants state that Celebrex® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
16 which was at all times adequate and comported with applicable standards of care and law.  
17 Defendants deny any wrongful conduct and deny the remaining allegations contained in this  
18 paragraph of the Complaint.

19 69. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
21 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
22 and is safe and effective when used in accordance with its FDA-approved prescribing  
23 information. Defendants state that the potential effects of Celebrex® were and are adequately  
24 described in its FDA-approved prescribing information, which was at all times adequate and  
25 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
26 deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this  
27 paragraph of the Complaint.

28 70. Defendants admit that the FDA Division of Drug Marketing, Advertising, and

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1 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and  
2 November 14, 2000. Defendants state that the referenced letters speak for themselves and  
3 respectfully refer the Court to the letters for their actual language and text. Any attempt to  
4 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph  
5 of the Complaint.

6 71. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.  
7 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to  
8 the letter for its actual language and text. Any attempt to characterize the letter is denied.  
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 72. Defendants state that the referenced article speaks for itself and respectfully refer the  
11 Court to the article for its actual language and text. Any attempt to characterize the article is  
12 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 73. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.  
14 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to  
15 the letter for its actual language and text. Any attempt to characterize the letter is denied.  
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 74. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
22 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
23 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
24 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
25 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
26 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
27 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
28 allegations in this paragraph of the Complaint.

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75. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

76. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

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1 77. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
6 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
7 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
8 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
9 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
10 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
11 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
12 allegations in this paragraph of the Complaint.

13 78. Defendants state that Celebrex® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
16 which at all times was adequate and comported with applicable standards of care and law.  
17 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
18 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
19 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
20 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
21 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
22 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
23 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
24 allegations in this paragraph of the Complaint.

25 79. Defendants state that Celebrex® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 80. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.

7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 81. Defendants deny the allegations in this paragraph of the Complaint.

10 82. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.

14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
15 the Complaint.

16 83. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.

20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 84. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
24 Decedent used Celebrex® and, therefore, deny the same. Defendants deny any wrongful  
25 conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the  
26 remaining allegations in this paragraph of the Complaint.

27 85. Defendants state that Celebrex® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

86. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

87. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

88. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

**Response to First Cause of Action: Negligence**

89. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

90. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
4 the Complaint.

5 91. Defendants state that this paragraph of the Complaint contains legal contentions to  
6 which no response is required. To the extent that a response is deemed required, Defendants  
7 admit that they had duties as are imposed by law but deny having breached such duties.  
8 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
9 FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
13 the Complaint.

14 92. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
16 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
17 and is safe and effective when used in accordance with its FDA-approved prescribing  
18 information. Defendants state that the potential effects of Celebrex® were and are adequately  
19 described in its FDA-approved prescribing information, which was at all times adequate and  
20 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
21 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

22 93. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
24 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
25 and is safe and effective when used in accordance with its FDA-approved prescribing  
26 information. Defendants state that the potential effects of Celebrex® were and are adequately  
27 described in its FDA-approved prescribing information, which was at all times adequate and  
28 comported with applicable standards of care and law. Defendants deny any wrongful conduct

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1 and deny the remaining allegations in this paragraph of the Complaint.

2 94. Defendants state that Celebrex® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
7 the Complaint.

8 95. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
10 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
11 and is safe and effective when used in accordance with its FDA-approved prescribing  
12 information. Defendants state that the potential effects of Celebrex® were and are adequately  
13 described in its FDA-approved prescribing information, which was at all times adequate and  
14 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
15 deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining  
16 allegations in this paragraph of the Complaint.

17 96. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' medical  
19 conditions and whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same.  
20 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent  
21 injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

22 97. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
23 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
24 Complaint.

25 98. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
26 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
27 Complaint.

28

**Response to Second Cause of Action: Strict Liability**

99. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

100. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

101. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

102. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining allegations in this paragraph of the Complaint.

103. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
4 remaining allegations in this paragraph of the Complaint, including all subparts.

5 104. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
7 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
8 and is safe and effective when used in accordance with its FDA-approved prescribing  
9 information. Defendants state that the potential effects of Celebrex® were and are adequately  
10 described in its FDA-approved prescribing information, which was at all times adequate and  
11 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
12 deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedent injury or  
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 105. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
19 remaining allegations in this paragraph of the Complaint.

20 106. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
22 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
23 and is safe and effective when used in accordance with its FDA-approved prescribing  
24 information. Defendants state that the potential effects of Celebrex® were and are adequately  
25 described in its FDA-approved prescribing information, which was at all times adequate and  
26 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
27 deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedent injury or  
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

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1 107. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 108. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
9 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
10 and is safe and effective when used in accordance with its FDA-approved prescribing  
11 information. Defendants state that the potential effects of Celebrex® were and are adequately  
12 described in its FDA-approved prescribing information, which was at all times adequate and  
13 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
14 deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining  
15 allegations in this paragraph of the Complaint.

16 109. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 110. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
24 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
25 and is safe and effective when used in accordance with its FDA-approved prescribing  
26 information. Defendants state that the potential effects of Celebrex® were and are adequately  
27 described in its FDA-approved prescribing information, which was at all times adequate and  
28 comported with applicable standards of care and law. Defendants deny any wrongful conduct

1 and deny the remaining allegations in this paragraph of the Complaint.

2 111. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
3 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
4 Complaint.

5 112. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
6 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
7 Complaint.

8 113. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
9 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
10 Complaint.

11 **Response to Third Cause of Action: Breach of Express Warranty**

12 114. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
13 Complaint as if fully set forth herein.

14 115. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
16 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
17 and is safe and effective when used in accordance with its FDA-approved prescribing  
18 information. Defendants state that the potential effects of Celebrex® were and are adequately  
19 described in its FDA-approved prescribing information, which was at all times adequate and  
20 comported with applicable standards of care and law. Defendants admit that they provided  
21 FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining  
22 allegations in this paragraph of the Complaint.

23 116. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
25 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
26 and is safe and effective when used in accordance with its FDA-approved prescribing  
27 information. Defendants state that the potential effects of Celebrex® were and are adequately  
28 described in its FDA-approved prescribing information, which was at all times adequate and

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1 comported with applicable standards of care and law. Defendants admit that they provided  
2 FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful  
3 conduct and deny the remaining allegations in this paragraph of the Complaint, including all  
4 subparts.

5 117. Defendants admit that they provided FDA-approved prescribing information regarding  
6 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this  
7 paragraph of the Complaint.

8 118. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
13 the Complaint.

14 119. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
19 the Complaint.

20 120. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
22 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that the potential  
23 effects of Celebrex® were and are adequately described in its FDA-approved prescribing  
24 information, which was at all times adequate and comported with applicable standards of care  
25 and law. Defendants admit that they provided FDA-approved prescribing information  
26 regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the  
27 Complaint.

28 121. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or

1 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
2 Complaint.

3 122. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
4 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
5 Complaint.

6 123. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
7 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
8 Complaint.

9 **Response to Fourth Cause of Action: Breach of Implied Warranty**

10 124. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
11 Complaint as if fully set forth herein.

12 125. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
13 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
14 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
15 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
16 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
17 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
18 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
19 the remaining allegations in this paragraph of the Complaint.

20 126. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants admit that they provided FDA-approved prescribing information regarding  
25 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 127. Defendants state that Celebrex® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 128. Defendants state that this paragraph of the Complaint contains legal contentions to  
4 which no response is required. To the extent that a response is deemed required, Defendants  
5 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
6 approved prescribing information. Defendants state that the potential effects of Celebrex®  
7 were and are adequately described in its FDA-approved prescribing information, which was at  
8 all times adequate and comported with applicable standards of care and law. Defendants deny  
9 any wrongful conduct, deny that they breached any warranty, and deny the remaining  
10 allegations in this paragraph of the Complaint.

11 129. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
13 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a  
14 prescription medication which is approved by the FDA for the following indications: (1) for  
15 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of  
16 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the  
17 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps  
18 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic  
19 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for  
20 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age  
21 and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 130. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
24 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
25 and is safe and effective when used in accordance with its FDA-approved prescribing  
26 information. Defendants state that the potential effects of Celebrex® were and are adequately  
27 described in its FDA-approved prescribing information, which was at all times adequate and  
28 comported with applicable standards of care and law. Defendants admit that they provided

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1 FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining  
2 allegations in this paragraph of the Complaint.

3 131. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
5 Decedent used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary  
6 case, Celebrex® was expected to reach users and consumers without substantial change from  
7 the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 132. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
10 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
11 and is safe and effective when used in accordance with its FDA-approved prescribing  
12 information. Defendants state that the potential effects of Celebrex® were and are adequately  
13 described in its FDA-approved prescribing information, which was at all times adequate and  
14 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
15 deny that they breached any warranty, and deny the remaining allegations in this paragraph of  
16 the Complaint.

17 133. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
18 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
19 Complaint.

20 134. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
21 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
22 Complaint.

23 135. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
24 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
25 Complaint.

26 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

27 136. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
28 Complaint as if fully set forth herein.

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1 137. Defendants state that this paragraph of the Complaint contains legal contentions to  
2 which no response is required. To the extent that a response is deemed required, Defendants  
3 admit that they had duties as are imposed by law but deny having breached such duties.  
4 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
5 FDA-approved prescribing information. Defendants state that the potential effects of  
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 138. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
15 the Complaint, including all subparts.

16 139. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 140. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
24 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
25 and is safe and effective when used in accordance with its FDA-approved prescribing  
26 information. Defendants state that the potential effects of Celebrex® were and are adequately  
27 described in its FDA-approved prescribing information, which was at all times adequate and  
28 comported with applicable standards of care and law. Defendants deny any wrongful conduct,

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1 deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining  
2 allegations in this paragraph of the Complaint.

3 141. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 142. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
11 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
12 and is safe and effective when used in accordance with its FDA-approved prescribing  
13 information. Defendants state that the potential effects of Celebrex® were and are adequately  
14 described in its FDA-approved prescribing information, which was at all times adequate and  
15 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
16 and deny the remaining allegations in this paragraph of the Complaint.

17 143. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
19 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
20 and is safe and effective when used in accordance with its FDA-approved prescribing  
21 information. Defendants state that the potential effects of Celebrex® were and are adequately  
22 described in its FDA-approved prescribing information, which was at all times adequate and  
23 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
24 and deny the remaining allegations in this paragraph of the Complaint.

25 144. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
27 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
28 and is safe and effective when used in accordance with its FDA-approved prescribing

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1 information. Defendants state that the potential effects of Celebrex® were and are adequately  
2 described in its FDA-approved prescribing information, which was at all times adequate and  
3 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
4 and deny the remaining allegations in this paragraph of the Complaint.

5 145. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
7 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
8 and is safe and effective when used in accordance with its FDA-approved prescribing  
9 information. Defendants state that the potential effects of Celebrex® were and are adequately  
10 described in its FDA-approved prescribing information, which was at all times adequate and  
11 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
12 and deny the remaining allegations in this paragraph of the Complaint.

13 146. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
15 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
16 and is safe and effective when used in accordance with its FDA-approved prescribing  
17 information. Defendants state that the potential effects of Celebrex® were and are adequately  
18 described in its FDA-approved prescribing information, which was at all times adequate and  
19 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
20 and deny the remaining allegations in this paragraph of the Complaint.

21 147. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
23 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
24 and is safe and effective when used in accordance with its FDA-approved prescribing  
25 information. Defendants state that the potential effects of Celebrex® were and are adequately  
26 described in its FDA-approved prescribing information, which was at all times adequate and  
27 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
28 and deny the remaining allegations in this paragraph of the Complaint.

1 148. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
2 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
3 Complaint.

4 149. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
5 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
6 Complaint.

7 150. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
8 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
9 Complaint.

10 **Response to Sixth Cause of Action: Unjust Enrichment**

11 151. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
12 Complaint as if fully set forth herein.

13 152. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
14 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
15 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
16 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
20 the remaining allegations in this paragraph of the Complaint.

21 153. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
23 Decedent used Celebrex® and, therefore, deny the same. Defendants deny the remaining  
24 allegations in this paragraph of the Complaint.

25 154. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and  
27 Decedent used Celebrex® and, therefore, deny the same. Defendants deny the remaining  
28 allegations in this paragraph of the Complaint.

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155. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

156. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

157. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Seventh Cause of Action:**

**State Consumer Fraud and Deceptive Trade Practices Act**

158. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

159. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants deny the remaining allegations in this paragraph of the Complaint.

160. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding whether Plaintiffs and Decedent used Celebrex® and,  
2 therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when  
3 used in accordance with its FDA-approved prescribing information. Defendants state that the  
4 potential effects of Celebrex® were and are adequately described in its FDA-approved  
5 prescribing information, which was at all times adequate and comported with applicable  
6 standards of care and law. Defendants deny any wrongful conduct and deny the remaining  
7 allegations in this paragraph of the Complaint.

8 161. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations regarding whether Plaintiffs and Decedent used Celebrex® and,  
10 therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when  
11 used in accordance with its FDA-approved prescribing information. Defendants state that the  
12 potential effects of Celebrex® were and are adequately described in its FDA-approved  
13 prescribing information, which was at all times adequate and comported with applicable  
14 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
15 Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of  
16 the Complaint.

17 162. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations regarding whether Plaintiffs and Decedent used Celebrex® and,  
19 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the  
20 Complaint.

21 163. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations regarding whether Plaintiffs and Decedent used Celebrex® and,  
23 therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when  
24 used in accordance with its FDA-approved prescribing information. Defendants state that the  
25 potential effects of Celebrex® were and are adequately described in its FDA-approved  
26 prescribing information, which was at all times adequate and comported with applicable  
27 standards of care and law. Defendants deny any wrongful conduct and deny the remaining  
28 allegations in this paragraph of the Complaint.

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164. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

165. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

166. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

167. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

168. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

169. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

### **Response to Prayer For Relief**

Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in paragraph of the Complaint headed "Prayer for Relief," including all subparts.

### **III.**

### **GENERAL DENIAL**

Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

## IV.

**AFFIRMATIVE DEFENSES**

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

**First Defense**

1. The Complaint fails to state a claim upon which relief can be granted.

**Second Defense**

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

**Third Defense**

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

**Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

**Fifth Defense**

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

**Sixth Defense**

6. Plaintiffs' action is barred by the statute of repose.

**Seventh Defense**

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs and Decedent were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

**Eighth Defense**

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

**Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

**Tenth Defense**

10. Any injuries or expenses incurred by Plaintiffs or Decedent were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

**Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs or Decedent.

**Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs' and Decedent's treating and prescribing physicians.

**Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fourteenth Defense**

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

**Fifteenth Defense**

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs and Decedent was prepared in accordance with the applicable standard of care.

**Sixteenth Defense**

16. Plaintiffs' and Decedent's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

**Seventeenth Defense**

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

**Eighteenth Defense**

18. Plaintiffs' and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

**Nineteenth Defense**

19. Plaintiffs and Decedent knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

**Twentieth Defense**

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by

the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

**Twenty-first Defense**

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

**Twenty-third Defense**

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fourth Defense**

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-sixth Defense**

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-seventh Defense**

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f

1 to § 6 of the Restatement (Third) of Torts: Products Liability.

2 **Twenty-eighth Defense**

3 28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts:  
4 Products Liability.

5 **Twenty-ninth Defense**

6 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead  
7 facts sufficient under the law to justify an award of punitive damages.

8 **Thirtieth Defense**

9 30. Defendants affirmatively aver that the imposition of punitive damages in this case  
10 would violate Defendants' rights to procedural due process under the Fourteenth Amendment of  
11 the United States Constitution and the Constitutions of the States of New York, Florida,  
12 Alabama, Arizona, and California, and would additionally violate Defendants' rights to  
13 substantive due process under the Fourteenth Amendment of the United States Constitution.

14 **Thirty-first Defense**

15 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and  
16 Fourteenth Amendments to the United States Constitution.

17 **Thirty-second Defense**

18 32. The imposition of punitive damages in this case would violate the First Amendment to  
19 the United States Constitution.

20 **Thirty-third Defense**

21 33. Plaintiffs' punitive damage claims are preempted by federal law.

22 **Thirty-fourth Defense**

23 34. In the event that reliance was placed upon Defendants' nonconformance to an express  
24 representation, this action is barred as there was no reliance upon representations, if any, of  
25 Defendants.

26 **Thirty-fifth Defense**

27 35. Plaintiffs and Decedent failed to provide Defendants with timely notice of any alleged  
28 nonconformance to any express representation.

1 **Thirty-sixth Defense**

2 36. To the extent that Plaintiffs' claims are based on a theory providing for liability without  
3 proof of causation, the claims violate Defendants' rights under the United States Constitution.

4 **Thirty-seventh Defense**

5 37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and  
6 labeling with respect to the subject pharmaceutical products were not false or misleading and,  
7 therefore, constitute protected commercial speech under the applicable provisions of the United  
8 States Constitution.

9 **Thirty-eighth Defense**

10 38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly  
11 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable  
12 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process  
13 protections afforded by the United States Constitution, the excessive fines clause of the Eighth  
14 Amendment of the United States Constitution, the Commerce Clause of the United States  
15 Constitution, and the Full Faith and Credit Clause of the United States Constitution, and  
16 applicable provisions of the Constitutions of the States of New York, Florida, Alabama,  
17 Arizona, and California. Any law, statute, or other authority purporting to permit the recovery  
18 of punitive damages in this case is unconstitutional, facially and as applied, to the extent that,  
19 without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the  
20 jury's discretion in determining whether to award punitive damages and/or the amount, if any;  
21 (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct  
22 will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state  
23 conduct, conduct that complied with applicable law, or conduct that was not directed, or did not  
24 proximately cause harm, to Plaintiffs or Decedent; (4) permits recovery of punitive damages in  
25 an amount that is not both reasonable and proportionate to the amount of harm, if any, to  
26 Plaintiffs or Decedent and to the amount of compensatory damages, if any; (5) permits jury  
27 consideration of net worth or other financial information relating to Defendants; (6) lacks  
28 constitutionally sufficient standards to be applied by the trial court in post-verdict review of any

1 punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of  
2 punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including,  
3 without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production*  
4 *Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*,  
5 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

6 **Thirty-ninth Defense**

7 39. The methods, standards, and techniques utilized with respect to the manufacture, design,  
8 and marketing of Celebrex®, if any, used in this case, included adequate warnings and  
9 instructions with respect to the product's use in the package insert and other literature, and  
10 conformed to the generally recognized, reasonably available, and reliable state of the  
11 knowledge at the time the product was marketed.

12 **Fortieth Defense**

13 40. The claims asserted in the Complaint are barred because Celebrex® was designed,  
14 tested, manufactured and labeled in accordance with the state-of-the-art industry standards  
15 existing at the time of the sale.

16 **Forty-first Defense**

17 41. If Plaintiffs or Decedent have sustained injuries or losses as alleged in the Complaint,  
18 upon information and belief, such injuries and losses were caused by the actions of persons not  
19 having real or apparent authority to take said actions on behalf of Defendants and over whom  
20 Defendants had no control and for whom Defendants may not be held accountable.

21 **Forty-second Defense**

22 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®  
23 was not unreasonably dangerous or defective, was suitable for the purpose for which it was  
24 intended, and was distributed with adequate and sufficient warnings.

25 **Forty-third Defense**

26 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,  
27 waiver, and/or estoppel.

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275 Battery Street, Suite 2000  
San Francisco, CA 94111

**Forty-fourth Defense**

44. Plaintiffs' claims are barred because Plaintiffs' and Decedent's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs and Decedent, and were independent of or far removed from Defendants' conduct.

**Forty-fifth Defense**

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs and Decedent.

**Forty-sixth Defense**

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs and Decedent did not incur any ascertainable loss as a result of Defendants' conduct.

**Forty-seventh Defense**

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

**Forty-eighth Defense**

48. The claims must be dismissed because Plaintiffs and Decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

**Forty-ninth Defense**

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

**Fiftieth Defense**

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

**Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs and Decedent.

**Fifty-second Defense**

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

**Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

**Fifty-fourth Defense**

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

**Fifty-fifth Defense**

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

**Fifty-sixth Defense**

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiffs and Decedent were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

**Fifty-seventh Defense**

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

**Fifty-eighth Defense**

58. Plaintiffs' claims are barred and/or limited by the provisions of the Arkansas Products Liability Act, Ark. Code Ann. § 16-116-101, et seq.

**Fifty-ninth Defense**

59. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Arkansas Civil Justice Reform Act of 2003, Ark. Code Ann. § 16-55-201 et seq.

**Sixtieth Defense**

60. In the event Plaintiffs recover a verdict or judgment against Defendants, then said verdict or judgment must be reduced pursuant to CPLR 4545(c), and/or other applicable State or Commonwealth statutes, by those amounts which have, or will, with reasonable certainty, replace or indemnify Plaintiffs, in whole or in part, for any past or future claimed medical expenses or other such economic loss, paid from any collateral source such as insurance, social security, workers' compensation or employee benefit programs.

**Sixty-first Defense**

61. In accordance with CPLR 1601 et seq., and/or other applicable State or Commonwealth statutes, the liability of Defendants, if any, to Plaintiffs for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities

1 contributing to the total liability for non-economic loss, including named parties and others over  
2 whom Plaintiffs could have obtained personal jurisdiction with due diligence.

3 **Sixty-second Defense**

4 62. In accordance with General Obligations Law 15-108, if Plaintiffs or Decedent executed  
5 a release or a covenant not to sue for a tortfeasor in this action, Plaintiffs' damage claim against  
6 Defendants is reduced to the extent of any amount stipulated by the release or covenant, or in  
7 the amount of consideration paid for it, or in the amount of the released tortfeasor's equitable  
8 share of the damages under CPLR 1401 et seq., whichever is greatest.

9 **Sixty-third Defense**

10 63. The conduct of Defendants and all activities with respect to the subject products were  
11 fair and truthful based upon the knowledge existing at the relevant time alleged in the  
12 Complaint. Therefore, Plaintiffs' claims under New York Business Corporation Law § 349 are  
13 barred.

14 **Sixty-fourth Defense**

15 64. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by  
16 Rule 1.120 of the Florida Rules of Civil Procedure.

17 **Sixty-fifth Defense**

18 65. Plaintiffs' claims are barred because Celebrex® was designed, manufactured, and  
19 marketed in accordance with the state of the art at the time of manufacture per § 768.1257,  
20 Florida Statutes.

21 **Sixty-sixth Defense**

22 66. Celebrex® is not defective or unreasonably dangerous, and Defendants are not liable  
23 because, at the time of sale or distribution of the Celebrex® alleged to have been used by  
24 Plaintiffs and Decedent, Defendants had complied with applicable regulations of the federal  
25 Food & Drug Administration and are entitled to application of § 768.1256, Florida Statutes.

26 **Sixty-seventh Defense**

27 67. Plaintiffs' and Decedent's injuries and damages, if any, were proximately caused by the  
28 negligence or fault of Plaintiffs and Decedent, or persons or parties whose identities are

unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs' recovery. Thus, Defendants are entitled to have their liability to the Plaintiffs, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of § 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to §§ 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262 (Fla. 1996).

**Sixty-eighth Defense**

68. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

**Sixty-ninth Defense**

69. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs' FDUTPA claim is improper and should be dismissed.

**Seventieth Defense**

70. The acts or practices of which Plaintiffs complain were and are required or specifically permitted by federal or state law. Therefore, Plaintiffs' FDUTPA claim is barred, fails to state a claim, and should be dismissed with prejudice.

**Seventy-first Defense**

71. Plaintiffs lack standing because Defendants did not engage in deceptive conduct with regard to Plaintiffs or otherwise.

**Seventy-second Defense**

72. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

**PRAYER**

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' and Decedent's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' and Decedent's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111

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May 15, 2008

GORDON & REES LLP

By: :                     /s/                      
Stuart M. Gordon  
sgordon@gordonrees.com  
Embarcadero Center West  
275 Battery Street, 20<sup>th</sup> Floor  
San Francisco, CA 94111  
Telephone: (415) 986-5900  
Fax: (415) 986-8054

May 15, 2008

TUCKER ELLIS & WEST LLP

By: :                     /s/                      
Michael C. Zellers  
michael.zellers@tuckerellis.com  
515 South Flower Street, Suite 4200  
Los Angeles, CA 90071  
Telephone: (213) 430-3400  
Fax: (213) 430-3409  
  
Attorneys for Defendants  
PFIZER INC., PHARMACIA  
CORPORATION, and G.D. SEARLE  
LLC

**JURY DEMAND**

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

May 15, 2008

GORDON & REES LLP

By: : \_\_\_\_\_/s/  
Stuart M. Gordon  
sgordon@gordonrees.com  
Embarcadero Center West  
275 Battery Street, 20<sup>th</sup> Floor  
San Francisco, CA 94111  
Telephone: (415) 986-5900  
Fax: (415) 986-8054

May 15, 2008

TUCKER ELLIS & WEST LLP

By: : \_\_\_\_\_/s/  
Michael C. Zellers  
michael.zellers@tuckerellis.com  
515 South Flower Street, Suite 4200  
Los Angeles, CA 90071  
Telephone: (213) 430-3400  
Fax: (213) 430-3409

Attorneys for Defendants  
PFIZER INC., PHARMACIA  
CORPORATION, and G.D. SEARLE  
LLC

Gordon & Rees, LLP  
275 Battery Street, Suite 2000  
San Francisco, CA 94111